# SAFETY DATA SHEET

CompCore™ AF Stack Cartridge & SyringeMix™; Base

## 1. Chemical Product and Company Identification

Product Name: CompCore<sup>TM</sup> AF Stack Cartridge & SyringeMix<sup>TM</sup> Nanofill Composite Dual-Cured

Core Build-up Material; Base

## **Premier® Dental Products Company**

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6000 Fax: 610-239-6171

Emergency Phone: 610-239-6000

## **Indications:**

CompCore<sup>TM</sup> AF is an automix, fluoride releasing, resin composite material designed for the direct fabrication of core build-ups.

#### **Contraindications:**

Do not use on patients with known sensitivity or allergy to resins. Wash exposed area completely to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.

### 2. Hazards Identification

Acute Health Hazards: May cause eye, respiratory and skin irritation in high concentration.

Chronic Health Hazards: Material is not known to cause significant health problems

Signs and Symptoms of Exposure: High concentrations can cause eye and respiratory irritation. Prolonged skin exposure

can cause dryness

**Primary routes of exposure:** Inhalation, skin contact, eye contact.

**Carcinogenicity:** NTP - no, OSHA - no, IARC – no.

Hazard symbol:

## 3. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phases
Triethylenglycoldimethacrylate	109-16-0	Irritant, R36/37/38/43
Co-initiator	10287-53-3	Irritant, R36/37/38
Photoinitiator	10373-78-1	Irritant, R36/37/38
Fumed Silica	67762-90-7	R36/37/38

## ✓ Additional information: For the wording of the listed risk phrases refer to section 16.

#### 4. First Aid Measures

In case of inhalation: If irritation occurs, take victim to open air. If breathing difficulty persists, consult a physician.

In case of skin contact: Wash with soap and water.

In case of eye contact: Flush with large quantities of water for 15 minutes. Consult a physician.

In case of ingestion: Consult a physician.

## 5. Fire-Fighting Measures

Flash point: N/A

**Extinguishing Media:** Carbon dioxide, water spray, dry chemical **Special Fire Fighting Procedures:** Avoid a direct jet of water.

Unusual Fire and Explosion Hazards: None.

#### 6. Accidental Release Measures

Environmental Precautions: Avoid seepage into sewers and water supplies.

Clean-Up Procedure: Contain spill and pick up material with a suitable absorbent material. Place

absorbent into a container

for later disposal.

# 7. Handling and Storage

**Handling:** No special measures necessary if handled according to instruction

Storage: Keep container tightly closed when not in use. Store in a cool, dry location. Keep material in original packaging.

Storage away from light, open flames, contamination and prolonged storage above 24°C (75°F).

## 8. Exposure Controls / Personal Protection

**Exposure Controls:** Use only in well-ventilated areas

**Respiratory Protection:** Avoid inhalation of vapors. No special protection under normal use. **Hand and Skin Protection:** Avoid unnecessary skin contact. Wear latex gloves when handling

Eye Protection: Wear safety goggles or safety glasses with side shields when handling

Hygiene Measures: Remove spilled material from skin and clothing. Do not eat or drink when handling this material

## 9. Physical and Chemical Properties

**Appearance:** White paste / Light-yellow paste/ Blue paste.

**Odor:** Specific odor **Boiling Point:** N/A

**Evaporation Rate** (Water = 1): N/A

**Vapor Density** (Air = 1): N/A **Solubility in Water:** Insoluble

# 10. Stability and Reactivity

Stability: This material is stable.

Hazardous Reactions: None if handled according to directions

**Hazardous Polymerization:** May occur. **Conditions to Avoid:** Heat, UV light

Incompatibility: Free radicals, reducing agents, heavy metal ions

Hazardous Decomposition Products: Carbon dioxide, water, carbon monoxide, acrylic decomposition products,

depending on conditions of heating and burning.

### 11. Toxicological Information

**Acute oral toxicity:** LD50 (rat) > 5000mg/KG

Irritation of Skin: Dryness and irritation possible upon prolonged exposure

Allergic Effects: Methacrylate sensitive individuals may exhibit an allergic reaction.

## 12. Ecological Information

Do not discharge into sewers or water supplies

Environmental persistence and degradability: no data available

Ecotoxicity: no data available

## 13. Disposal Considerations

May be disposed of in landfill or Incinerator In accordance with local, state and federal regulations

### 14. Transport Information

14.1 Transport at land ADR RID

UN Number Kemler Number

**Packing Group** 

Proper shipping name

14.2 Transport at sea ADNR IMDG

**UN Number** 

EMS MFAG

**Packing Group** 

Proper shipping name

14.3 Air transport ICAO / IATA-DGR

**UN Number** 

Proper shipping name Subsidiary Risk

Labels

**Packing Group** 

U.S. DOT Shipping Name: Not Regulated

U.S. DOT Hazard Class: None U.N./N.A. Number: None

**U.S. DOT Packing Group:** None **Other:** Not considered hazardous cargo

## 15. Regulatory Information

This product requires classification according to the criteria of EC. The product is a medical device according to the EC-directive 93/42.

15.1 UN Number:

15.2 National regulations:

15.3 EU number:

15.4 Hazard symbols: 🕚

15.5 Hazard designation: Irritant

15.6 Risk phrases: 36/37/38 Irritating to eyes, respiratory system, and skin

43 May cause sensitization by skin contact

15.7 Safety phrases S: 2, 9, 16, 23, 26, 28, 24/25, 37/39

2 Keep out of the reach of children.

9 Keep container in a well-ventilated place.

16 Keep away from sources of ignition - No smoking.

23 Do not breathe vapour.

26 In case of contact with eyes, rinse immediately with

plenty of water and seek medical advise.

28 After contact with skin, wash immediately with

plenty of water and soap.

24/25 Avoid contact with skin and eyes.

37/39 Wear suitable gloves and eye/face protection.

**U.S.-O.S.H.A. Status:** This material is not hazardous under the criteria of the U.S Federal Hazard Communication Standard.

### 16. Other Information

Premier's revision date: 04/30/2015

**Revision Number: 5** 

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

### **Relevant R-phrases**

36/37/38 Irritating to eyes, respiratory system, and skin

43- May cause sensitization by skin contact

**Irritant** 

Material should be maintained in original containers. Empty containers should not be re-used.

# **ANSI/NFPA 704 Data**

Fire = 1

Health = 0

Reactivity = 0

Specific Hazard = None

Supplier's date: 07/30/2014

This SDS is offered solely for your information, consideration and investigation. This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. Premier Dental Products Company provides no warranties; either expressed or implied, and assumes no responsibility for the accuracy or completeness of data contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

051504 Rev5

# SAFETY DATA SHEET

CompCore™ AF Stack Cartridge & SyringeMix™; Catalyst

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Core Build-up Material; Catalyst

## Premier® Dental Products Company

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#### **Indications:**

CompCore<sup>TM</sup> AF is an automix, fluoride releasing, resin composite material designed for the direct fabrication of core build-ups.

#### **Contraindications:**

Do not use on patients with known sensitivity or allergy to resins. Wash exposed area completely to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.

#### 2. Hazards Identification

Acute Health Hazards: May cause eye, respiratory and skin irritation in high concentration.

Chronic Health Hazards: Material is not known to cause significant health problems

Signs and Symptoms of Exposure: High concentrations can cause eye and respiratory irritation. Prolonged skin exposure can cause dryness.

Primary routes of exposure: Inhalation, skin contact, eye contact.

Carcinogenicity: NTP - no, OSHA - no, IARC - no.

Hazard symbol:



## 3. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phases
Triethylenglycoldimethacrylate	109-16-0	Irritant, R36/37/38/43
Benzoyl Peroxide	94-36-0	Explosive, Irritant
Fumed Silica	67762-90-7	R36/37/38

## ✓ Additional information: For the wording of the listed risk phrases refer to section 16.

#### 4. First Aid Measures

In case of inhalation: If irritation occurs, take victim to open air. If breathing difficulty persists, consult a physician.

In case of skin contact: Wash with soap and water.

In case of eye contact: Flush with large quantities of water for 15 minutes. Consult a physician.

In case of ingestion: Consult a physician.

## 5. Fire-Fighting Measures

Flash point: N/A

**Extinguishing Media:** Carbon dioxide, water spray, dry chemical **Special Fire Fighting Procedures:** Avoid a direct jet of water.

Unusual Fire and Explosion Hazards: None.

#### 6. Accidental Release Measures

Environmental Precautions: Avoid seepage into sewers and water supplies.

Clean-Up Procedure: Contain spill and pick up material with a suitable absorbent material . Place

absorbent into a container

for later disposal.

### 7. Handling and Storage

Handling: No special measures necessary if handled according to instruction

Storage: Keep container tightly closed when not in use. Store in a cool, dry location. Keep material in original packaging.

Storage away from light, open flames, contamination and prolonged storage above 24°C (75°F).

### 8. Exposure Controls / Personal Protection

Exposure Controls: Use only in well-ventilated areas

**Respiratory Protection:** Avoid inhalation of vapors. No special protection under normal use. **Hand and Skin Protection:** Avoid unnecessary skin contact. Wear latex gloves when handling

Eye Protection: Wear safety goggles or safety glasses with side shields when handling,

Hygiene Measures: Remove spilled material from skin and clothing. Do not eat or drink when handling this material

### 9. Physical and Chemical Properties

**Appearance:** Light grey paste.

Odor: Specific odor Boiling Point: N/A

**Evaporation Rate** (Water = 1): N/A **Vapor Density** (Air = 1): N/A **Solubility in Water:** Insoluble

### 10. Stability and Reactivity

**Stability:** This material is stable.

Hazardous Reactions: None if handled according to directions

**Hazardous Polymerization:** May occur. **Conditions to Avoid:** Heat, UV light

Incompatibility: Free radicals, reducing agents, heavy metal ions

Hazardous Decomposition Products: Carbon dioxide, water, carbon monoxide, acrylic decomposition products,

depending on conditions of heating and burning.

# 11. Toxicological Information

Acute oral toxicity: LD50 (rat) > 5000mg/KG

Irritation of Skin: Dryness and irritation possible upon prolonged exposure

Allergic Effects: Methacrylate sensitive individuals may exhibit an allergic reaction.

### 12. Ecological Information

Do not discharge into sewers or water supplies

Environmental persistence and degradability: no data available

Ecotoxicity: no data available

## 13. Disposal Considerations

May be disposed of in landfill or Incinerator In accordance with local, state and federal regulations

## 14. Transport Information

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UN Number Kemler Number

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Proper shipping name Subsidiary Risk

Labels

**Packing Group** 

U.S. DOT Shipping Name: Not Regulated

U.S. DOT Hazard Class: None

U.N./N.A. Number None

U.S. DOT Packing Group: None Other: Not considered hazardous cargo

## 15. Regulatory Information

This product requires classification according to the criteria of EC. The product is a medical device according to the EC-directive 93/42.

15.1 UN Number:

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43 May cause sensitization by skin contact

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2 Keep out of the reach of children.

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26 In case of contact with eyes, rinse immediately with

plenty of water and seek medical advise.

28 After contact with skin, wash immediately with

plenty of water and soap.

24/25 Avoid contact with skin and eyes.

37/39 Wear suitable gloves and eye/face protection.

**U.S.-O.S.H.A. Status:** This material is not hazardous under the criteria of the U.S. Federal Hazard Communication Standard.

16. Other Information

Premier's revision date: 04/30/2015

**Revision Number: 5** 

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

### **Relevant R-phrases**

36/37/38 Irritating to eyes, respiratory system, and skin 43 May cause sensitization by skin contact Irritant

Material should be maintained in original containers. Empty containers should not be re-used.

#### **ANSI/NFPA 704 Data**

 $\begin{aligned} & Fire = 1 \\ & Health = 0 \end{aligned}$ 

Reactivity = 0

Specific Hazard = None

Supplier's date: 07/30/2014

This SDS is offered solely for your information, consideration and investigation. This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. Premier Dental Products Company provides no warranties; either expressed or implied, and assumes no responsibility for the accuracy or completeness of data contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

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